

SAFETY DATA SHEET**Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

Product Name:	Butordyne Injection
Product Code:	504270 (10 mL); 520355 (50 mL)
Recommended Use:	Analgesic and sedative for use in horses, dogs and cats.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street Rutherford NSW 2320 Australia
Customer Centre:	1800 02 3312
National Poisons Information Centre:	13 1126 (Australia-wide)
Emergency Telephone Number:	1800 02 3312 (9a.m. – 5p.m.)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: STOT RE - Category 2

GHS Pictograms:



Health hazard

Signal Word*: Warning

Hazard Statements*: May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements*:

Prevention
Do not breathe vapours.

Response
Get medical advice if you feel unwell.

Disposal
Dispose of contents / container in accordance with local / national regulations.

* N.B.: These statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Butorphanol tartrate	58786-99-5	< 1.5 %
Benzethonium chloride	121-54-0	0.01%
Other ingredients determined to be not hazardous		To 100%

Section 4: FIRST AID MEASURES

First Aid Measures:	Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have product container or label at hand.
Inhalation:	Is unlikely to present an inhalation problem. If respiratory symptoms do occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen. Seek medical assistance immediately.
Ingestion:	Is unlikely to present an ingestion hazard. If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 13 1126.
Skin:	If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.
Eye:	If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If eye irritation persists, get medical advice/attention.
Injection:	Treat as for needlestick injury. Wash area well and disinfect. If other symptoms become evident, seek medical advice.
Advice to Doctor:	Treat as for opioid overdose.

Section 5: FIRE FIGHTING MEASURES

Flash Point:	Not flammable. Not combustible.
Hazardous Combustion Products:	If involved in a fire may emit toxic and corrosive fumes.
Extinguishing Media:	There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
Protective Equipment:	Protective gloves and boots and breathing apparatus
HAZCHEM Code:	None specified

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal:	Wear appropriate protective clothing. For small spills, wash area well with excess water. For large spills, exclude non-essential people from the area. Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.
Protective Clothing:	For appropriate personal protective equipment see section 8.
Environmental Precautions:	Prevent from entering drains, waterways or sewers. If contamination of drains and waterways occurs, advise local authority.

Section 7: HANDLING AND STORAGE

Handling:	This is a Schedule 8 (Controlled Drug) product and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Possession without authority is illegal. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin, eyes and inhalation of vapours. Take care to avoid accidental self-injection. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.
Storage:	Store below 25°C (Air Conditioning). Protect from light. Store vials upright after initial broaching. Discard unused portion 8 weeks after first broaching. Keep out of reach of children.
Other Information:	Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

- Exposure Limits:** No exposure limits have been assigned for this product. Do not handle until all safety precautions have been read and understood.
- Protective Equipment:** Safety glasses with eye side shields or chemical goggles. Chemical protective gloves, e.g. PVC. Safety footwear or safety gumboots, e.g. rubber.
- Engineering Controls:** Handle in a well-ventilated area.
- Hygiene Precautions:** Do not drink, eat or smoke when handling this product. Wash hands after use.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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| Appearance: | Clear, colourless liquid, free of particulate matter. | Vapour Pressure: | Not available. |
| Odour: | Not available. | Vapour density: | Not available. |
| Odour threshold: | Not available. | Relative density: | Not applicable. |
| pH: | 3.5 -4.5. | Specific Gravity: | ~1.01. |
| Melting Point: | Not available. | Solubility in Water: | Soluble. |
| Boiling Point: | Not available. | Partition coefficient: | Not applicable. |
| Flash Point: | Not flammable. | Auto-ignition temperature: | Not available. |
| Evaporation Rate: | Not available. | Decomposition temperature: | Not available. |
| Flammability: | Not applicable. | Viscosity: | Not available. |
| Upper flammability limits: | Not applicable. | | |
| Lower flammability limits: | Not applicable. | | |

Section 10: STABILITY AND REACTIVITY

- Stability:** When stored appropriately this product should show no significant degradation within the Expiry period shown on the label.
- Hazardous Polymerisation:** Not known to occur.
- Materials to Avoid:** Avoid oxidising agents.

Section 11: TOXICOLOGICAL INFORMATION

- Inhalation:** Is unlikely to present an inhalation problem due to non-volatile nature of product.
- Ingestion:** Not acutely toxic. Significant oral exposure is considered to be unlikely.
Butorphanol tartrate: Oral LD₅₀: 315 mg/kg (rat);
Benzethonium chloride : Oral LD₅₀ : 338 mg/kg (mouse).
- Skin:** Not skin irritant.
- Eye:** Not eye irritant.
- Injection:** Effects may vary in severity according to the quantity involved, from localised site reaction (pain, redness, swelling) to a more acute systemic reaction.
Butorphanol tartrate: LD₅₀ (rat): 17 mg/kg (intravenous), 255 mg/kg (intramuscular);
Benzethonium chloride: LD₅₀ (rat): 19 mg/kg (intravenous), 119 mg/kg (subcutaneous).
- Chronic Effects:** Prolonged continuous use of butorphanol tartrate may result in physical dependence or tolerance (a decrease in response to a given dose). May cause damage to organs through prolonged or repeated exposure. Possible target organs include the central nervous system, cardiovascular system, respiratory system and the gastrointestinal system.
- Mutagenicity:** Not known to be mutagenic.
- Carcinogenicity:** Not known to be carcinogenic.
- Reproductive Toxicity:** Not considered to affect reproduction, based on the results of animal studies.

Section 12: ECOLOGICAL INFORMATION

- Ecotoxicity:** Not known to be ecotoxic.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Butorphanol tartrate	No data available	No data available	No data available	No data available
Benzethonium chloride	HIGH	No data available	LOW	LOW

Section 13: DISPOSAL INFORMATION

- Product Disposal:** Dispose of product only by using according to label or at an approved landfill.
- Container Disposal:** Wrap with paper and place in garbage.

Section 14: TRANSPORT INFORMATION

- Dangerous Goods Classification:** Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.
- HAZCHEM Code:** None specified.

Section 15: REGULATORY INFORMATION

- Poisons Schedule:** S8
- APVMA Registration Nos:** 67699

Section 16: OTHER INFORMATION

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein do so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

This SDS **supercedes the version created on 4 March 2014**. It includes addition of product code 520355 (50 mL) in section 1 and a GHS pictogram in Section 2.

Legend

CAS No. means a unique number assigned to a chemical by the Chemical Abstracts Service.

GHS means the '*Globally Harmonized System of Classification and Labelling of Chemicals, 3rd Revised Edition*', published by the United Nations.

LD₅₀ means the median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.

PVC means Polyvinyl chloride.

References

ChemIDPlus, entries for Butorphanol (RN: 42408-82-2) and Benzethonium chloride (RN: 121-54-0).

VSDb (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>), entry for butorphanol.

END OF SDS